

**Amendment and Response**

Applicant: David Francischelli et al.

Serial No.: 10/056,806

Filed: January 25, 2002

Docket No.: M190.135.101

Title: SYSTEM AND METHOD OF PERFORMING AN ELECTROSURGICAL PROCEDURE

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**REMARKS**

This Response is in reply to the Office Action mailed December 18, 2003. In that Office Action, the Examiner rejected claims 1-10, 19, 20, and 22-31 under 35 U.S.C. §102(b) as being anticipated by Panescu et al., U.S. Patent No. 5,688,267 ("Panescu"). Claims 1-11, 15, and 22-31 were rejected under 35 U.S.C. §103(a) as being unpatentable over Panescu. Claims 16-18 were rejected under 35 U.S.C. §103(a) as being unpatentable over Panescu and further in view of Mulier et al., U.S. Patent No. 5,897,553 ("Mulier"). Claim 21 was rejected under 35 U.S.C. §103(a) as being unpatentable over Panescu in view of the teachings of Jackson et al., U.S. Patent No. 5,383,874 ("Jackson"), and Edwards, U.S. Patent No. 6,009,877 ("Edwards"). Claims 12-14 were objected to as being dependent upon a rejected base claim. The Examiner's indication that claims 12-14 would be allowable if re-written in independent form is noted with appreciation. With this Response, claims 1 and 22 have been amended and claim 32 has been added. Claims 1-32 are pending in the application and are presented for reconsideration and allowance.

**35 U.S.C. §102 and §103 Rejections**

Independent claim 1 was rejected under 35 U.S.C. §102(b) as being anticipated by Panescu and under 35 U.S.C. §103(a) as being unpatentable over Panescu. Amended, independent claim 1 relates to a method of making a lesion at a living tissue at target site. The method includes providing an electrosurgical system having an electrosurgical instrument with an electrode and a power source with multiple settings, determining a desired depth for the lesion, selecting a desired power setting, and applying electrical energy to the electrode in contact with the living tissue. Energy is applied to the living tissue for a recommended energization time period based upon the desired lesion depth and the desired power setting. The recommended energization time period is determined prior to the step of applying electrical energy to the electrode. The step of selecting a desired power setting is completed prior to determining the recommended energization time period. Such limitations are not taught or otherwise suggested by Panescu.

Panescu relates to a method for sensing multiple temperature conditions during tissue ablation. The method of Panescu describes a physician pre-selecting a targeted ablation time, a

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maximum power setting, and a maximum temperature to achieve a desired lesion depth (column 11, lines 14-20). Based upon these physician selected parameters, the master controller 98 selects a fixed power level and controls the rate at which the electrode 16 is cooled to complete the ablation procedure within the pre-selected parameters (column 11, lines 27-35).

As described in Applicants' previous Response, Panescu teaches using a pre-determined or pre-selected time period to identify the proper power setting prior to ablation and, as such, the time period is determined prior to selection of a power setting, which is converse to the limitations of amended, independent claim 1 in which the time period is determined based upon the selected power setting. By selecting the power setting prior to selecting the energization time period and selecting both parameters prior to ablation, the electrode can be drawn across the target tissue site at a consistent speed, thereby, creating a relatively uniform lesion without concern that the variations in power "P" or time "t" during the procedure (as taught by Panescu) will cause certain portions of the target tissue site to be ablated at different rates and with varying results as compared to other portions of the target site.

The passage cited by the Examiner in the latest Office Action does not alter the basis of the explicitly described process of Panescu. In the explicitly described process, Panescu teaches pre-selected time "t" that was pre-selected by a physician. During ablation, the controller 98 controls the rate at which the electrode 16 is cooled to establish and maintain the sensed electrode temperature "T1" at the level called for by the "D<sub>50C</sub>" boundary function (column 11, lines 27-35). As such, Panescu describes a physician selecting parameters prior to ablation and a controller 98 controlling the parameters during ablation.

The Examiner cited passage (column 12, lines 16-25) merely states that the controller 98 can fix any one or more of the control parameters (i.e., temperature "T1," power "P," and time "t") and vary the remaining one or more of the control parameters to achieve the desired depth "D<sub>50C</sub>" (i.e., remain within the D<sub>50C</sub> temperature boundary function). Notably, the cited passage only relates to the controller 98 determining which of the parameters "T1," "P," or "t" are varied. Since the controller 98 determines the parameters "T1," "P," and "t" during ablation, the cited passage only relates to parameters fixed/varied during, rather than prior to, ablation and does not alter what parameters the physician initially inputs into the controller 98.

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Consequently, although the cited passage of Panescu may teach varying “t” with respect to a predetermined power setting “P” during the ablation process, Panescu fails to teach determining the initial energization time period prior to ablation based upon a predetermined power setting as recited in claim 1. Nevertheless, it is inherent that to start ablation, initial values of the parameters “T1,” “P,” and “t” must be determined. The only teaching of Panescu for determining initial or starting parameters is a physician entering a time “t” and a maximum power level “P<sub>MAX</sub>” and the controller 98 determining the power setting “P” based upon the physician selected time “t” and maximum power level “P<sub>MAX</sub>.” This is the converse of claim 1. Further, if time “t” stays fixed during ablation, then the claim 1 limitation of a “recommended energization time period based upon a selected power setting” is not met. If, instead, time “t” varies during ablation, then the claim 1 limitation of selecting a “recommended energization time period prior to the step of applying electrical energy to the electrode” is not met. Therefore, Panescu teaches away from the limitations of amended, independent claim 1.

For at least the above described reasons, Panescu fails to teach or otherwise suggest the limitations of amended, independent claim 1. Accordingly, Applicants believe amended, independent claim 1 to be allowable.

Claims 2-10, 19, and 20 were similarly rejected under 35 U.S.C. §102(b) as being anticipated by Panescu. In addition, claims 2-11 and 15 were rejected under 35 U.S.C. §103(a) as being unpatentable over Panescu. Each of claims 2-11, 15, 19, and 20 depend from and incorporate the limitations of amended, independent claim 1. As described above, Panescu fails to teach or otherwise suggest limitations of amended, independent claim 1. As a result, dependent claims 2-11, 15, 19, and 20 are similarly believed to be allowable over Panescu.

Claims 16-18 were rejected under 35 U.S.C. §103(a) as being unpatentable over Panescu and further in view of Mulier. Claim 21 was rejected under 35 U.S.C. §103(a) as being unpatentable over Panescu in view of the teachings of Jackson and Edwards. Each of claims 16-18 and 21 depend from and incorporate the limitations of amended, independent claim 1, which is believed to be allowable. Moreover, since Panescu teaches against the limitations of amended, independent claim 1, Mulier, Jackson, and Edwards fail to alter the above described analysis. Consequently, dependent claims 16-18 and 21 are also believed to be allowable over the cited references.

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Independent claim 22 was rejected under 35 U.S.C. §102(b) as being anticipated by Panescu and under 35 U.S.C. §103(a) and being unpatentable over Panescu. Amended, independent claim 22 relates to an electrosurgical system for performing an electrosurgical procedure on living tissue. The system includes an electrosurgical instrument, a power source, and an energization look-up table. The power source has multiple available power settings and is electrically connected to the electrosurgical instrument. The energization look-up table corresponds with the electrosurgical instrument and includes a power setting data set, a lesion depth data set, and energization time period information organized as a dependent variable of the power setting and lesion data sets. The power setting data set includes at least two of the multiple available power settings of the power source. The energization look-up table is adapted to identify a recommended energization time period based upon a cross-reference of a selected power setting relative to the power setting data set and a desired lesion depth relative to the lesion depth data set. Panescu fails to teach or otherwise suggest such limitations.

More specifically, Panescu fail to teach or otherwise suggest an energization look-up table adapted to identify a recommended energization time period based upon a cross-reference of a selected power setting and a desired lesion depth and including a power setting data set that includes two of the multiple available power settings of the power source. The D<sub>50C</sub> Boundary Function table of Panescu organizes data in rows and columns with time as a constant for the entire table (see column 11). Accordingly, multiple tables are produced with each table having a single constant time value (column 11, lines 45-47). In this manner, a pre-selected time value is used to select the proper table, and the selected table is subsequently used to determine the remaining ablation parameters. Since each table only includes data for a single time period, reversing the process of Panescu to select a time period based on a lesion depth and a power setting would require cumbersome reference to multiple tables in direct contrast to the energization look-up table of claim 1. Therefore, no single table of Panescu is adapted to identify a recommended energization time period based upon cross-reference of a selected power setting and a desired lesion depth. Rather, multiple tables would have to be referenced to determine the recommended energization time period in direct contrast to the energization look-up table of claim 1.

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Furthermore, argumentatively assuming Panescu teaches pre-selecting power, rather than time, the tables used would be altered accordingly. More specifically, the power and time values would supplant one another in the corresponding tables such that each table would include a single power setting and multiple time values. With this in mind, no single table of Panescu could otherwise be used to determine a recommended energization time period based on a pre-selected power setting and lesion depth would include a power setting data set that includes at least two of the multiple available power settings of the power source as recited in amended, independent claim 22. Consequently, Panescu fails to teach or otherwise suggest an energization look-up table as recited in amended, independent claim 22. As a result, amended, independent claim 22 is believed to be allowable.

Claims 23-27 were rejected under 35 U.S.C. §102(b) as being anticipated by Panescu and under 35 U.S.C. §103(a) as being unpatentable over Panescu. Each of claims 23-27 depend from and incorporate the limitations of amended, independent claim 22. As described above, amended, independent claim 22 is believed to be allowable over Panescu. Accordingly, dependent claims 23-27 are also believed to be allowable over Panescu.

Independent claim 28 was rejected under 35 U.S.C. §102(b) as being anticipated by Panescu and under 35 U.S.C. §103(a) as being unpatentable over Panescu. Independent claim 28 relates to an electrosurgical system for performing an electrosurgical procedure. The system includes an electrosurgical instrument having an electrode at a distal portion, a power source electrically connected to the electrosurgical instrument for selectively energizing the electrode and having multiple available settings, and a means for electronically selecting a recommended energization time period by reference to pre-determined length of time information that relates to the electrosurgical instrument and based upon a selected power setting selected prior to energizing the electrode and a desired lesion depth. For similar reasons as described with respect to independent claims 1 and 22, Panescu fails to teach or otherwise suggest the limitations of independent claim 28.

As described above, Panescu teaches a physician pre-selecting the time period prior to controller 98 selecting the power setting prior to ablation. This sequence of events is in direct contrast to the limitations of independent claim 28, which recites selecting a recommended energization time period based upon a power setting selected prior to energizing the electrode.

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Furthermore, as described above, the Panescu passage cited by the Examiner (column 12, lines 16-25) fails to alter this analysis as the passage only relates to varying ablation parameters during ablation based upon sensed electrode temperatures and, therefore, does not effect events occurring before ablation (i.e. energization of the electrode) has begun nor does it teach selecting time based on the power setting. As a result, Panescu fails to teach or otherwise suggest the limitations of claim 28. Therefore, independent claim 28 is believed to be allowable.

Claims 29-31 were rejected under 35 U.S.C. §102(b) as being anticipated by Panescu and under 35 U.S.C. §103(a) as being unpatentable over Panescu. Each of claims 29-31 depends from independent claim 28. As described above, independent claim 28 is not taught or otherwise suggested by any of the cited references and is believed to be allowable. For at least these reasons, dependent claims 29-31 are also believed to be allowable.

**New Claim 32**

New claim 32 depends from and incorporates the limitations of independent claim 1. Claim 32 adds the additional limitation that the step of selecting a desired power setting is performed by a surgeon, wherein per the claim 1 limitations, electrical energy is applied to the electrode in contact with the living tissue at the desired power setting. This additional limitation is in direct contrast to the method of Panescu, which teaches a physician selecting a maximum power setting boundary and a master controller 98 selecting the power setting to actually be used when the electrode is applied to tissue (column 11, lines 21-35).

Having a surgeon select the power setting to be used during the application of electrical energy, as recited in new claim 32, benefits the ablation procedure. For one, the surgeon has additional control and actual knowledge of the power setting being used and, thereby, can more precisely match movement of the electrode along the living tissue to the power setting to decrease the probability of mishaps. Furthermore, a surgeon selecting a desired power setting can utilize protocols and guidelines developed (as described on page 12, line 8 – page 13, line 8 of the current application) not only to maintain the power setting below a recommended maximum temperature (like the controller 98 of Panescu) but also taking into account probable ablation time, the probability of pops, and other concerns and parameters for a particular procedure and a particular patient. As such, the direct physician/surgeon control of the power setting used during

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ablation results in more predictable tissue response and, therefore, will likely lead to less surprises or complications during the procedure. With this in mind, new claim 32 is believed to be allowable over the cited references.

**Allowable Subject Matter**

Claims 12-14 were identified by the Examiner as being allowable subject matter, but were rejected for being dependent upon a rejected base claim. Claims 12-14 depend from independent claim 1, which, as described above, is believed to be allowable. Therefore, claims 12-14 are no longer believed to be dependent upon a rejected base claim. Accordingly, claims 12-14 are believed to be allowable in dependent form.

**CONCLUSION**

In light of the above, Applicant believes independent claims 1, 22, and 28, and the claims depending therefrom, are in condition for allowance. Notice to that effect is respectfully requested.

The Patent Office is hereby authorized to charge the amount of \$18.00 (to cover the additional claim fees set forth under 37 C.F.R. 1.16(b)(c)) to Deposit Account No. 50-0471 and any additional fees that may be required.

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The Examiner is invited to contact the Applicants' Representative at the below-listed telephone number if there are any questions regarding this response.

Respectfully submitted,

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**CERTIFICATE UNDER 37 C.F.R. 1.8:**

The undersigned hereby certifies that this paper or papers, as described herein, are being deposited in the United States Postal Service, as first class mail, in an envelope address to: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on this 3<sup>rd</sup> day of March, 2004.

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